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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,421	04/05/2005	Peter G. Schultz	54A-000170US	6734

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/530,421	Applicant(s) SCHULTZ ET AL.	
	Examiner Kagnew H. Gebreyesus	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claim 1 is a linking claim for claims 2-8 and 17, Claim 9 is links claims 10-16 and claim 18 links claims 18-22, claim 23 is links to claims 24-28.

Group 1, claim(s) 2-8 and 17 are drawn to a composition comprising an O-RS with SEQ ID NO: 18 or a conservative variant thereof wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 18 with a keto amino acid.

Group 2, claim(s) 2-8 and 17 are drawn to a composition comprising an O-RS with SEQ ID NO: 19 or a conservative variant thereof wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 19 with a keto amino acid.

Group 3, claim(s) 2-8 and 17 are drawn to a composition comprising an O-RS with SEQ ID NO: 20 or a conservative variant thereof wherein the O-RS variant preferentially

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aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 20 with a keto amino acid.

Group 4, claims 10-16 are drawn to a cell comprising an O-tRNA, an O-RS with SEQ ID NO: 18 or a conservative variant thereof, a keto amino acid, wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 18 with a keto amino acid.

Group 5, claims 10-16 are drawn to a cell comprising an O-tRNA, an O-RS with SEQ ID NO: 19 or a conservative variant thereof, a keto amino acid, wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 19 with a keto amino acid.

Group 6, claims 10-16 are drawn to a cell comprising an O-tRNA, an O-RS with SEQ ID NO: 20 or a conservative variant thereof, a keto amino acid, wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 20 with a keto amino acid.

Group 7, claims 18-22 are drawn to an artificial DNA, vector and host cell comprising a polynucleotide that encodes the polypeptide of SEQ ID NO: 18.

Group 8, claims 18-22 are drawn to an artificial DNA, vector and host cell comprising a polynucleotide that encodes the polypeptide of SEQ ID NO: 19.

Group 9, claims 18-22 are drawn to an artificial DNA, vector and host cell comprising a polynucleotide that encodes the polypeptide of SEQ ID NO: 20.

Group 10, claims 24-28 are drawn to a method of producing a protein in a cell with a keto amino acid at a specified position using the O-RS of SEQ ID NO: 18 or a conservative variant thereof wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 18 with said keto amino acid.

Group 11, claims 24-28 are drawn to a method of producing a protein in a cell with a keto amino acid at a specified position using the O-RS of SEQ ID NO: 19 or a conservative variant thereof wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 19 with said keto amino acid.

Group 12, claims 24-28 are drawn to a method of producing a protein in a cell with a keto amino acid at a specified position using the O-RS of SEQ ID NO: 20 or a conservative variant thereof wherein the O-RS variant preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 20 with said keto amino acid.

The technical feature of claim 1 is an orthogonal aminoacyl-tRNA synthetase (O-RS), which preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 18 with a keto-amino acid. When broadly interpreted, a polypeptide comprising an amino acid sequence of SEQ ID NO: 18 need not have more than 2 contiguous amino acids

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common with SEQ ID NO: 18 with the ability to aminoacylate an O-tRNA with a keto amino acid. Schultz et al teach methods and compositions comprising ORS that can aminoacylate an OtRNA with the unnatural amino acid, meta-acyl-L-phenylalanine. Specifically Schultz et al disclose SEQ ID NO: 49-53 that are tRNA synthetase mutants (ORS) that incorporate a ketone unnatural amino acids into proteins.

Therefore the technical feature in Group 1, which is an ORS which preferentially aminoacylates an O-tRNA with an efficiency of at least 50% of the efficiency of a polypeptide comprising an amino acid sequence of SEQ ID NO: 18 (an ORS with 2 or more contiguous amino acids identical in SEQ ID NO: 18) which can aminoacylate an O-tRNA with a keto amino acid is obvious. Thus the technical feature of Group 1 is not a special technical feature. Furthermore the technical feature of Group 1-12 is drawn to or depends on each of the O-RS sequences of SEQ ID NO: 18, SEQ ID NO: 19 and SEQ ID NO: 20. These sequences represent distinct structures and function (by virtue of the genus of keto amino acids in the linking claims). Therefore the technical feature of Groups 1-12 is not a special technical feature defined by PCT Rule 13.2.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

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commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Kagnew Gebreyesus PhD.
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KG


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER